# CORPORATE INTEGRITY AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND WALGREEN CO.

#### I. PREAMBLE

Walgreen Co. ("Walgreens") hereby agrees to enter into this Corporate Integrity
Agreement ("CIA") with the Office of Inspector General ("OIG") of the United States
Department of Health and Human Services ("HHS"). Walgreens also agrees to implement
reasonable policies, procedures, and practices to effect compliance by its corporate officers
and directors, employees, and all persons whom Walgreens may engage for the delivery of
prescription services or the submission of claims for prescription services with the terms of
this agreement and the requirements of Medicare, Medicaid and all other Federal health
care programs (as defined in 42 U.S.C. § 1320a-7b(f)).

Contemporaneously with this CIA, Walgreens is entering into a settlement agreement with the United States for conduct relating to the partial filling of prescriptions, and this CIA is incorporated into that settlement agreement by reference. In addition, Walgreens has or will soon enter individual settlement agreements with certain States relating to the partial filling of prescriptions and this CIA is also incorporated into those agreements by reference.

#### II. TERM OF THE AGREEMENT

The period of the compliance obligations assumed by Walgreens under this CIA

shall be four (4) years. The effective date of the CIA will be the date of the final signature on this CIA.

# III. CORPORATE INTEGRITY OBLIGATIONS

A. Compliance Officer and Supporting Personnel. Within ninety (90) days of the effective date of this CIA, Walgreens shall appoint a Compliance Officer who shall be responsible for overseeing the development of and coordinating the implementation of those policies and procedures necessary to effect compliance with the requirements set forth in this CIA, and with the requirements of Medicare, Medicaid, and all other federal health care programs. The Compliance Officer shall be at least a director-level employee of Walgreens and shall make regular reports regarding compliance matters directly to Walgreens' CEO and/or to the Board of Directors of Walgreens. The Compliance Officer shall be authorized to report directly to the Board of Directors of Walgreens at any time. If the identity of the Compliance Officer changes during the term of this CIA, Walgreens shall notify the OIG, in writing, within thirty (30) days of such change.

The Compliance Officer shall have the authority to and will regularly engage a group of upper-level representatives from various departments within Walgreens to support and assist him or her in fulfilling the responsibilities associated with this CIA. The Compliance Officer shall engage the appropriate corporate personnel as necessary to implement the requirements of this CIA (e.g., members of Walgreens' legal department, the pharmacy department, the training and development department and the audit department.) Within ninety (90) days of the effective date of this CIA, the Compliance Officer shall identify and notify a representative from each of the appropriate departments that he or she will be called upon to support and assist the Compliance Officer in fulfilling the responsibilities of this CIA.

B. Code of Conduct. Within ninety (90) days after the effective date of this CIA, Walgreens shall develop and implement a written Code of Conduct. Walgreens' Pharmacy Law, Policies & Ethics Statement ("the Statement") may serve as the Code of Conduct if it is amended to emphasize Walgreens' commitment to compliance with all applicable Federal and State health care statutes, regulations and guidelines, including the requirements of Medicare, Medicaid and other Federal health care programs, and to emphasize Walgreens' commitment to prepare and submit accurate billings consistent with Medicare, Medicaid and other Federal health care program regulations and instructions. The Code of Conduct shall be initially approved by the President/CEO of Walgreens and subsequently adopted by the Board of Directors.

Within ninety (90) days of the effective date of the CIA, the Code of Conduct shall be distributed to all Walgreens' employees and, where applicable, contractors who provide pharmacy services or prepare or submit claims to Federal and State health care programs in Walgreens' facilities or on Walgreens' premises (hereinafter "pharmacy/billing employees"). In addition, and also within ninety (90) days of the effective date of this CIA, Walgreens shall post the Code of Conduct in prominent locations accessible to all pharmacy/billing employees.

Within one hundred fifty (150) days of the effective date of this CIA, each of Walgreens' pharmacy/billing employees shall certify, in writing or electronically, that he or she has read the Code of Conduct, understands it and will abide by it. New pharmacy/billing employees shall receive the Code of Conduct and complete the required certification within four (4) weeks after the commencement of their employment or within ninety (90) days of the effective date of this CIA, whichever is later. The Compliance Officer and appropriate personnel should be available to explain any provision of the Code of Conduct, if necessary. All pharmacy/billing employees of Walgreens shall certify on an annual basis that they have read and understand the Code of Conduct, and that they will abide by it. Walgreens will annually review the Code of Conduct and will revise it as it

deems necessary. Revisions to the Code of Conduct shall be distributed and made available to pharmacy/billing employees within thirty (30) days of initiating such change.

C. Policies and Procedures. Except as otherwise noted below, within ninety (90) days of the effective date of this CIA, Walgreens shall develop and initiate implementation of reasonable written Policies and Procedures regarding compliance with this CIA and with all applicable Federal health care and State health care statutes, regulations, and guidelines, including the requirements of Medicare, Medicaid and other Federal health care programs.

Included among the other issues that they address, the Policies and Procedures shall specifically address the manner in which Walgreens shall submit claims to Federal and state health care programs for prescriptions that are only partially filled (i.e., where only a portion of the prescribed amount of medication is furnished on a given date to the customer who is a beneficiary of one of those programs). The Policies and Procedures shall provide that pharmacy/billing employees shall "reverse" claims submitted once it is determined that the pharmacy has insufficient inventory to immediately and fully fill any prescription. The Policies and Procedures shall ensure that, after such initial claim is reversed, a claim for a partially filled prescription may be submitted only for the quantity of medication available for immediate delivery. When Walgreens receives and prepares the remainder amount of the prescription for dispensing, it will "reverse" or adjust the claim submitted for the partial amount and submit a claim for the whole amount of the prescription.

Walgreens is undertaking significant computer system changes in order to implement the partial fill policies specified herein. These changes have not been completed as of the effective date of this CIA. Walgreens commits itself to using its best efforts to diligently finalize and implement these computer system changes as soon as possible, but not later than one (1) year from the effective date of this CIA. Walgreens shall keep the OIG apprised of the status of its computer system changes and shall notify the OIG in the event of any significant delay in implementation of these computer system changes. Until the company-wide rollout of these computer system changes, Walgreens will continue to use its present policies for submitting claims in situations where prescriptions are partially filled. Walgreens shall commence to develop those Policies and Procedures specifically addressing the new partial fill computer procedures within ninety (90) days of the effective date of this CIA and shall it initiate implementation of those Policies and Procedures within ninety (90) days of the completion of the company-wide rollout of its computer system changes.

Walgreens shall ensure that it does not receive a second dispensing fee from any Federal or state health care program for dispensing the remainder of a partially filled prescription to a program beneficiary. The Policies and Procedures shall provide that Walgreens shall not collect any additional co-payment amounts from customers that exceed the total co-payment amount applicable to the prescription at issue.

The Policies and Procedures shall require Walgreens, if less than the full amount of prescribed medication is provided to a customer, to affirmatively inform the customer that he or she was furnished with less medication than prescribed and instruct the customer of the need to obtain an additional amount of the medication in order to comply with his or her physician's care instructions. The Policies and Procedures shall prohibit Walgreens from requiring any customer to make any statement, in writing or otherwise, which is false or misleading in order to receive the prescription which the customer is desiring to have Walgreens fill.

The Policies and Procedures shall include disciplinary guidelines and methods for employees to make complaints and notifications about compliance issues to Walgreens' Compliance Officer through a confidential disclosure program. Walgreens shall update the Policies and Procedures whenever appropriate. An index of the Policies and Procedures will be provided to the OIG in the Implementation Report. The Policies and Procedures will be available to the OIG upon request.

These Policies and Procedures shall be made available to all Walgreens' pharmacy/billing employees. In addition, the pharmacy/billing employees shall receive training related to these Policies and Procedures. Pharmacy Supervisors shall be available to explain any and all Policies and Procedures if necessary.

**D. Training and Education.** Within ninety (90) days of Walgreens' completion of its company-wide rollout of its computer system changes relating to partially filled prescriptions, Walgreens shall provide appropriate training to each of its

pharmacy/billing employees as specified below. Walgreens' training program shall be a substantive and thorough program that provides meaningful training on the items listed herein. Specifically, this training shall: (1) explain the requirements of this CIA; (2) cover Walgreens' Code of Conduct; (3) cover Walgreens' Policies and Procedures, including those pertaining to the submission of accurate claims for prescriptions that were only partially dispensed to customers; (4) cover applicable reimbursement rules and statutes; (5) cover the personal obligation of each pharmacy/billing employee to ensure that billings are accurate; (6) cover the legal sanctions for improper billings; (7) provide examples of proper and improper billing practices; and (8) advise employees how potential violations of the applicable rules or of Walgreens' Policies and Procedures should be handled and that any failure to comply may result in disciplinary action, up to and including termination of employment. Persons providing the training must have the requisite expertise and qualifications to conduct the required training.

New pharmacy/billing employees shall receive the training described above within thirty (30) days of the beginning of their employment or within ninety (90) days after the completion of Walgreens' company-wide rollout of its computer system changes relating to partially filled prescriptions, whichever is later. If a new pharmacy/billing employee has any responsibility for the submission of pharmacy claims for payment prior to completing this training, a Walgreens pharmacy/billing employee who has completed the training shall supervise or review all of the untrained person's work regarding the submission of claims.

Each pharmacy/billing employee shall certify, in writing or electronically, that he or she has received the required training. The certification shall specify the date the training was received and Walgreens shall maintain a record of the date of training of each pharmacy/billing employee. Walgreens shall provide the OIG with an outline of the training materials in its Annual Reports and shall make its training materials available to the OIG upon request.

E. Audits and Disclosures. During each year of this CIA, Walgreens shall perform audits of its billing, claims submission and compliance practices. Each audit will cover a twelve (12) month period. Walgreens may conduct these audits using its internal audit staff. In such a case, Walgreens shall annually engage the services of an independent review organization, such as an accounting firm or consulting firm, to review whether Walgreens has performed the internal audit in conformance with the sample procedures in Appendix D of SOP 99-1 as they apply to Walgreens. Walgreens shall annually request the independent review organization to produce a report on its procedures and findings, which reports shall be included in the Annual Reports. The independent review organization must have expertise in billing, claims submission, coding, reporting and other requirements of the Medicare, Medicaid, and other Federal health care programs from which Walgreens seeks reimbursement.

Walgreens will conduct two separate internal reviews each year. The first review will be a billing audit of Walgreens' claims submissions to the Medicare, Medicaid and all other Federal health care programs to determine compliance with all applicable statutes, regulations, and policies. The second review will determine whether Walgreens is in compliance with this CIA.

The following guidelines outline the minimum items that shall be addressed in the billing audits:

- 1. an assessment of Walgreens' billing and claims submission system (including how the system operates, its internal controls and their effectiveness, the strengths and weaknesses of the system, and whether it complies with the statutes, regulations and other requirements of Medicare, Medicaid and other Federal health care programs from which Walgreens seeks reimbursement);
- 2. an audit and analysis of whether Walgreens is submitting accurate claims to Medicare, Medicaid, and other Federal health care programs. The audit will cover a statistically valid sample of the claims submitted during the time covered by the audit;

- 3. an assessment of Walgreens' procedures to correct inaccurate billings and claims submissions to Medicare, Medicaid, and other Federal health care programs;
- 4. an assessment of whether, when Walgreens only partially fills a prescription, it submits a claim to the applicable Federal or State health care program only for the quantity available for immediate delivery; and
- 5. an assessment of the steps Walgreens is taking to bring its operations into compliance or to correct any problems identified by the audits.

The second review Walgreens will conduct is an assessment of whether Walgreens' policies, procedures, and operations comply with the terms of this CIA.

Walgreens shall include a copy of the results of its internal audits in its Annual Report to the OIG. The billing audit section of that Annual Report shall: 1) explain the methodology used to make each determination required by the audit; 2) explain the audit results; and 3) identify any overpayments.<sup>2</sup> The listing of overpayments should include the amount of money, the program (e.g., Medicare, Medicaid (identified by State)), and name of the contractor to which the refund was made.

If any audit reveals that there have been any billing, claims submission, coding or other policies, procedures and/or practices that resulted in an overpayment and/or material deficiency,<sup>3</sup> Walgreens shall notify the payor (e.g., the Medicare fiscal intermediary or carrier or the state Medicaid program) within thirty (30) days of discovering the material deficiency or overpayment. If Walgreens learns of any overpayment, Walgreens shall promptly (but in no event later than sixty (60) days after discovering the overpayment)

For purposes of this CIA, an "overpayment" shall mean the amount of money Walgreens has received in excess of the amount due and payable under the Medicare, Medicaid, or other Federal health care program's statutes and regulations. Walgreens shall not be responsible for identifying any overpayments that are unknown to it and resulted from errors made by the health care programs or payors or their agents.

For purposes of this CIA, a "material deficiency" shall mean anything that involves: (i) a substantial overpayment or a substantial improper payment relating to the Medicare and/or Medicaid programs; and/or (ii) conduct or policies that clearly violate the Medicare and/or Medicaid statutes, regulations or directives issued by the Health Care Financing Administration and/or its agents. A material deficiency may be the result of an isolated event or a series of occurrences.

notify the payor and make appropriate refunds.<sup>4</sup> Further, Walgreens shall take remedial steps within sixty (60) days (or such additional time as may be reasonably necessary) to correct the problem, including preventing said material deficiency from reoccurring.

If Walgreens has identified a material deficiency, contemporaneous with its notification to the payor as provided above, Walgreens shall notify OIG of: (1) the material deficiency (including Walgreens' findings and any overpayment amounts); (2) Walgreens' findings concerning the material deficiency; (3) Walgreens' action(s) to correct and prevent such material deficiency from reoccurring; (4) the payor's name, address, and contact person where any overpayment was sent; (5) the date of the check and check number (or electronic transaction number) on which any overpayment was repaid.

In the event that the OIG reasonably determines that it is necessary to conduct an independent audit or review to determine whether or the extent to which Walgreens is complying with its obligations under this CIA, Walgreens agrees to pay for the reasonable cost of any such audit or review by the OIG or any of its designated agents. Prior to conducting any such audit or review, the OIG will notify Walgreens that the audit or review will be undertaken and allow Walgreens an opportunity to provide any necessary information to the OIG.

F. Confidential Disclosure Program. Within ninety (90) days after the effective date of this CIA, Walgreens shall establish a confidential disclosure program, which may include measures such as a "hotline," to enable its employees to disclose any issues or questions relating to the Medicare, Medicaid, or any other Federal health care program policies, practices or procedures that the individual alleges to be improper. This individual

In order to process the refund, the payor requires certain information. Therefore, the notice to the payor should: (1) state that the refund is being made pursuant to the terms of this CIA; and should describe and identify (2) the complete circumstances surrounding the overpayment; (3) the methodology by which the overpayment was determined; (4) the amount of the overpayment; (5) any claim-specific information used to determine the overpayment (e.g., beneficiary health insurance number, claim number, service date, and payment date); and (6) the provider identification number under which the repayment is being made.

shall have the opportunity to make this disclosure to the Compliance Officer or some other person who is not in the reporting individual's chain of command. If Walgreens utilizes a hotline, it shall publicize the existence of the hotline to its pharmacy/billing employees (e.g., by posting the hotline number in prominent places or distributing it via e-mail to its employees). Such hotline shall be incorporated into an existing disclosure program. The confidential disclosure program shall emphasize a non-retribution, non-retaliation policy, and shall include a reporting mechanism for anonymous, confidential communication. Upon receipt of a complaint, the Compliance Officer (or designee) shall investigate the complaint and make a good faith attempt to elicit all relevant information from individuals reporting alleged misconduct and from other sources. If any disclosure or complaint is sufficiently specific that it reasonably (1) permits a determination of the appropriateness of the alleged improper practice, and (2) provides opportunity for the taking of corrective action, the Compliance Officer (or designee) shall conduct an internal review of the allegations set forth in such disclosure and ensure that proper follow-up is conducted.

The Compliance Officer shall maintain a confidential disclosure log, which shall include a record of each allegation received, status of the investigation of the allegation, and any corrective action taken in response to the investigation.

#### G. Excluded Individuals.

For purposes of this CIA, an "Ineligible Person" is defined to mean any individual or entity who: (i) is currently excluded, suspended, debarred or otherwise ineligible to participate in Medicare, Medicaid or other Federal health care programs; or (ii) has been convicted of a criminal offense related to the provision of health care items or services and has not been reinstated in the Medicare, Medicaid or other Federal health care programs after a period of exclusion, suspension, debarment, or ineligibility.

Walgreens agrees prospectively to not hire or, where applicable, contract with any Ineligible Persons in situations where those Ineligible Persons will be engaged in the

delivery of prescription services or the submission of claims for payment for those services. To avoid employing or contracting with any such Ineligible Person, Walgreens agrees to make reasonable inquiry as to the status of any individual or entity who is a prospective employee or contractor by reviewing the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://www.arnet.gov/epls) and the HHS/OIG Cumulative Sanction Report (available through the Internet at http://www.dhhs.gov/progorg/oig). (This list and report are hereinafter referred to collectively as the "Exclusion Lists.") Walgreens agrees to conduct this review on the local store level prior to engaging the services of that individual or entity. In addition, within thirty (30) days of engaging the services of that individual or entity, Walgreens agrees to conduct this review at the corporate level.

Walgreens also agrees to make a reasonable inquiry, within ninety (90) days of the effective date of this CIA, into whether any of its current pharmacy/billing employees is an Ineligible Person. Walgreens may satisfy this obligation by comparing its list of current pharmacy/billing employees against the Exclusion Lists. If Walgreens learns that any of its current pharmacy/billing employees is an Ineligible Person, it shall follow the procedures set forth in the remainder of this section.

If Walgreens receives notice that a current pharmacy/billing employee is charged with a criminal offense related to Medicare, Medicaid or any Federal health care program, or is suspended from Medicare, Medicaid or any Federal health care program or proposed for exclusion from Medicare, Medicaid or any Federal health care program during his or her employment or contract with Walgreens, Walgreens will remove such employee from responsibility for, or involvement with, Walgreens' business operations related to the Federal health care programs until the resolution of such criminal action, suspension, or proposed exclusion.

If Walgreens receives notice that a current pharmacy/billing employee is or has become an Ineligible Person, Walgreens will remove such employee from responsibility

for, or involvement with, Walgreens' business operations related to Medicare, Medicaid or any Federal health care programs and shall remove such employee from any position for which the individual's salary or the services rendered by the employee are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the person is reinstated into participation in the Federal health care programs.

H. Notification of Investigations/Proceedings. If Walgreens learns it is the subject of any ongoing federal or state government investigation or any federal or state government initiated legal proceeding involving an allegation that it has committed a crime or has engaged in fraudulent activities or other knowing misconduct, Walgreens shall notify the OIG of this fact within thirty (30) days of discovering it. The notification shall describe the allegation, identify the investigating or prosecuting agency, and describe the status of such investigation or legal proceeding. Walgreens shall also notify OIG in writing within thirty (30) days of the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the proceedings.

#### IV. OIG INSPECTION, AUDIT AND REVIEW RIGHTS

In addition to any other rights the OIG may have by statute, regulation, or contract, Walgreens agrees to grant certain inspection, audit and review rights to the OIG. The OIG or its duly authorized representative(s) or agents, subject to any properly asserted legal privilege, may examine Walgreens' books, records, and other documents and supporting materials for the purpose of verifying and evaluating: i) Walgreens' compliance with the terms of this CIA, and (ii) Walgreens' compliance with the requirements of the Medicare, Medicaid and other Federal health care programs. Walgreens will make available the documentation described above at all reasonable times for inspection, audit or reproduction.

Furthermore, for purposes of this provision, the OIG or its duly authorized representative(s) or agents may interview any of Walgreens' employees who consent to be interviewed at their place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and the OIG. Walgreens agrees to assist the OIG in contacting and arranging interviews with such employees upon the OIG's request. Walgreens employees may elect to be interviewed with or without a representative of Walgreens present. The interviews will be conducted in accordance with all applicable statutes, regulations and rules, including, but not limited to, the Citizens Protection Act of 1998.

# V. IMPLEMENTATION AND ANNUAL REPORTS

Within one-hundred-and-twenty (120) days after the effective date of this CIA, Walgreens shall submit a written report to the OIG summarizing the status of implementation of the requirements of this CIA ("Implementation Report"). This Implementation Report shall include:

- (1) the name, address, phone number and position description of the Compliance Officer and the group of departmental representatives who support and assist the Compliance Officer in fulfilling the requirements of the CIA;
- (2) a copy of Walgreens' Code of Conduct;
- (3) a certification by the Compliance Officer that the Policies and Procedures required by this agreement have been developed and are being implemented in accordance with section III.C, and that each pharmacy/billing employee has or will receive training about these Policies and Procedures;
- (4) an index of the Policies and Procedures in accordance with section III.C;
- (5) a description of the training being implemented pursuant to this agreement in accordance with section III.D;

- (6) the identity of the independent review organization that will conduct a review of Walgreens' internal audits and the proposed start and completion dates of Walgreens' first internal audits;
- (7) a description of the confidential disclosure program implemented pursuant to this agreement; and
- (8) a summary of the personnel or contract actions taken with regard to Ineligible Persons.

Thereafter, Walgreens shall submit to the OIG an Annual Report, with respect to the status and findings of Walgreens' compliance activities.

### The Annual Reports shall include:

- (1) any change in the identity or position description of the Compliance Officer and the group of departmental representatives assisting the Compliance Officer;
- (2) Compliance Officer certification that the Code of Conduct was distributed to all pharmacy/billing employees and that Walgreens notified such employees of any changes or amendments to the Code of Conduct;
- (3) Compliance Officer certification that all pharmacy/billing employees have been trained on Walgreens' Policies and Procedures;
- (4) an outline of the Walgreens' training program;
- (5) notification of any changes in the Policies and Procedures as they relate to the issue of the partial filling of prescriptions and the reason for any such change;
- (6) the results of Walgreens' internal billing and compliance audits, the finding reports from the independent review organizations, and a summary of any responsive action that Walgreens plans or has undertaken in response to these reports;
- (7) a summary of material deficiencies discovered and reported during the course of the previous twelve (12) months and the status of corrective actions taken to address those problems;

- (8) a report of the aggregate overpayments that have been returned to the Medicare, Medicaid, and other Federal health care programs that were discovered as direct or indirect result of implementing this CIA.

  Overpayment amounts should be broken down into the following categories: Medicare, Medicaid (report each applicable state separately) and other Federal health care programs.
- (9) a description of the disclosures received under Walgreens' confidential disclosure program, the status of actions taken as a result of such disclosures, and a copy of the confidential disclosure log;
- (10) a description of any personnel or contract action taken by Walgreens as a result of its obligations with regard to Ineligible Persons;
- (11) a description of any ongoing investigation or legal proceeding conducted or brought by a federal or state governmental entity involving an allegation that Walgreens has committed a crime or has engaged in fraudulent activities. The statement shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation, legal proceeding or requests for information;
- (12) a certification by the Compliance Officer verifying that: (a) Walgreens is in compliance with all the requirements of this CIA, to his or her knowledge, and (b) the Compliance Officer has reviewed the Annual Report and has made reasonable inquiry regarding its content and believes, upon inquiry, that the information contained in it is accurate and truthful.

The first Annual Report shall be received by the OIG no later than one year and sixty (60) days after the effective date of the CIA. Subsequent Annual Reports shall be submitted no later than the anniversary dates of the first Annual Report.

#### VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated or agreed by the parties subsequent to the effective date of this CIA, all notifications and reports required under the terms of this CIA shall be submitted to the entities and persons listed below or to such other address as one party so notifies the other:

#### OIG:

Civil Recoveries Branch - Compliance Unit

Office of Counsel to the Inspector General

Office of Inspector General

U.S. Department of Health and Human Services

330 Independence Avenue, SW

Cohen Building, Room 5527

Washington, DC 20201

Phone: (202) 619-2078

Fax: (202) 205- 0604

#### **WALGREENS:**

Chester Young Allan M. Resnick

Compliance Officer Law Department

Walgreen Co. Walgreen Co.

200 Wilmot Road 200 Wilmot Road

MS #2252 MS #2252

Deerfield, Illinois 60015 Deerfield, Illinois 60015

Phone: (847) 914-5100 Phone: (847) 914-3570

Fax: (847) 914-2825

#### VII. DOCUMENT AND RECORD RETENTION

Walgreens shall maintain for inspection all documents and records relating to reimbursement from Medicare, Medicaid and other Federal health care programs and

relating to compliance with this CIA. Walgreens shall maintain these records for a period of one year longer than the duration of this CIA (or longer if otherwise required by law).

#### VIII. BREACH AND DEFAULT PROVISIONS

Walgreens shall fully, timely and in good faith comply with all of the obligations to which it agrees in this CIA. Such compliance shall be expected throughout the compliance period required by this CIA. The OIG will act in good faith and give due consideration to all facts and circumstances in making determinations as to compliance with this CIA and the imposition of penalties.

#### A. Stipulated Penalties for Failure to Comply with Certain Obligations.

As a contractual remedy, Walgreens and OIG hereby agree that Walgreens' failure to comply with certain obligations set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

- (1) A Stipulated Penalty of \$5,000 (which shall begin to accrue on the day after the date the obligation became due) for each day Walgreens fails to have in place any of the following:
  - a. a Compliance Officer and a group of supporting personnel;
  - b. written Policies and Procedures;
  - c. a training program;
  - d. procedures for conducting the annual internal audits and the independent review of those audits; and
  - e. a confidential disclosure program.

- (2) A Stipulated Penalty of \$5,000 (which shall begin to accrue on the day after the date the obligation became due) for each day Walgreens fails to meet any of the deadlines to submit an Implementation Report and the Annual Reports to the OIG.
- (3) A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Walgreens hires or contracts with any Ineligible Person or if Walgreens fails to follow the procedures set forth in section III.G if any of its current pharmacy/billing employees is or becomes an Ineligible Person during the course of his/her employment. This Stipulated Penalty shall not be demanded if Walgreens can demonstrate that it did not discover that the individual was an Ineligible Person after making good faith reviews at both store level and headquarters level of the Exclusion Lists as described in section III.G and that it acted in accordance with the procedures outlined in section III.G immediately upon notice of ineligibility.
- (4) A Stipulated Penalty of \$3,000 (which shall begin to accrue on the day after the date the obligation became due) for each day Walgreens fails to grant reasonable access to the information or documentation necessary to exercise OIG's inspection, audit and review rights.
- (5) A Stipulated Penalty of \$2,000 (which shall begin to accrue ten (10) days after the date that OIG provides notice to Walgreens of the failure to comply) for each day Walgreens fails to fully and adequately comply with any obligation of this CIA. In its notice to Walgreens, the OIG shall state the specific grounds for its determination that Walgreens has failed to comply fully and adequately with the CIA obligation(s) at issue.

#### B. Payment of Stipulated Penalties.

(1) <u>Demand Letter</u>. If the OIG determines that Walgreens has failed to comply with any of the obligations described in section VIII.A and Stipulated Penalties are appropriate, the OIG shall notify Walgreens by personal service or certified mail of: (i) Walgreens' failure to comply; and (ii) the OIG's exercise of its contractual right to demand payment of

the Stipulated Penalties (this notification is hereinafter referred to as the "Demand Letter"). Within fifteen (15) days of receipt of the Demand Letter, Walgreens shall either: (i) cure the breach to the OIG's satisfaction and pay the applicable Stipulated Penalties; or (ii) request a hearing before an HHS administrative law judge (ALJ) to dispute the OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in section VIII.D. In the event Walgreens elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Walgreens cures, to the OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter shall be considered a material breach of this CIA and shall be grounds for the imposition of a Material Breach Penalty under section VIII.C.

- (2) Timely Written Requests for Extensions. Walgreens may submit a timely written request for an extension of time to perform any act or file a notification or report required by this CIA. The OIG shall not unreasonably refuse such request.

  Notwithstanding any other provision in this section, if OIG grants the timely written request, Stipulated Penalties shall not begin to accrue unless and until Walgreens fails to meet the deadline granted by the extension. Notwithstanding any other provision in this section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until two (2) business days after Walgreens receives OIG's written denial of such a request. A "timely written request" is defined as a request in writing received by OIG at least five (5) business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.
- (3) Form of Payment. Payment of the Stipulated Penalties shall be made by certified or cashier's check payable to "Secretary of the Department of Health and Human Services," and submitted to the OIG at the address set forth in section VI.
- (4) Independence from Material Breach Determination. Except as otherwise noted, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for the OIG's determination that Walgreens has materially breached this CIA,

which decision shall be governed by the provisions in section VIII.C, below.

- C. Monetary Penalty for Material Breach of this CIA.
- 1) Material Breach Defined. A material breach of this CIA means: (i) a failure by Walgreens to report a known material deficiency, take corrective action and pay the appropriate refunds, as provided in section III.E; (ii) repeated or flagrant violations of the obligations under this CIA, including, but not limited to, the obligations addressed in section VIII.A; or (iii) a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with section VIII.B above.
- (2) Notice of Material Breach and Intent to Collect Material Breach Penalty. The parties agree that a material breach of this CIA by Walgreens constitutes grounds for the OIG to impose an enhanced stipulated penalty that is separate and apart from the Stipulated Penalties described in section VIII.A-B. This monetary penalty (hereinafter referred to as the "Material Breach Penalty") shall be \$20,000 per day. Upon a determination by the OIG that Walgreens has materially breached this CIA and that a Material Breach Penalty should be imposed, the OIG shall notify Walgreens by certified mail of: (i) Walgreens' material breach; and (ii) the OIG's intent to exercise its contractual right to impose the Material Breach Penalty (this notification is hereinafter referred to as the "Notice of Material Breach Letter"). In its Notice of Material Breach Letter, the OIG shall state the specific grounds for its determination that Walgreens has materially breached this CIA.
- (3) Opportunity to Cure. Walgreens shall have thirty-five (35) days from the date of receipt of the Notice of Material Breach Letter to demonstrate to the OIG's reasonable satisfaction that:
  - (a) Walgreens is in full compliance with this CIA;
  - (b) the alleged material breach has been cured; or
  - (c) the alleged material breach cannot be cured within the thirty-five (35) day period, but that (i) Walgreens has begun to take action to cure the material

breach; (ii) Walgreens is pursuing such action with due diligence; and (iii) Walgreens has provided to the OIG a reasonable timetable for curing the material breach.

(4) Penalty Letter. If, at the conclusion of the thirty-five (35) day period, Walgreens fails to satisfy the requirements of section VIII.C.3, the OIG may impose the Material Breach Penalty on Walgreens and the penalty will begin to accrue on that day. The OIG will notify Walgreens in writing of its determination to impose the Material Breach Penalty (this letter shall be referred to hereinafter as the "Material Breach Penalty Letter"). Within fifteen (15) days of receipt of the Material Breach Penalty Letter, Walgreens shall either: (i) cure the material breach to the OIG's satisfaction and pay the applicable Material Breach Penalty; or (ii) request a hearing before an HHS administrative law judge (ALJ) to dispute the OIG's determination of material breach, pursuant to the agreed upon provisions set forth below in section VIII.D. In the event Walgreens elects to request an ALJ hearing, the Material Breach Penalties shall continue to accrue until Walgreens cures, to the OIG's satisfaction, the alleged material breach in dispute.

# D. Dispute Resolution.

(1) Review Rights. Upon the OIG's delivery to Walgreens of its Demand Letter or of its Material Breach Penalty Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under the obligation of this CIA, Walgreens shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. § 1005 as if they applied to the Stipulated Penalties or Material Breach Penalties sought pursuant to this CIA. Specifically, the OIG's determination to demand payment of Stipulated Penalties or Material Breach Penalties shall be subject to review by an ALJ and/or the Departmental Appeals Board (DAB) in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties or Material Breach Penalties shall be made within fifteen (15) days of the date of receipt of the Demand Letter or the Penalty

Letter.

- (2) Stipulated Penalties Review. Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (i) whether Walgreens was in full and timely compliance with the obligations of this CIA for which the OIG demands payment; and, (ii) the period of noncompliance. Walgreens shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. If the ALJ finds for the OIG with regard to whether there was a breach of this CIA and orders Walgreens to pay Stipulated Penalties, such Stipulated Penalties shall be due and payable twenty (20) days after the ALJ issues such a decision notwithstanding that Walgreens may request review of the ALJ decision by the DAB.
- (3) Material Breach Review. Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding regarding imposition of the Material Breach Penalty shall be: (a) whether Walgreens was in material breach of this CIA; (b) whether Walgreens had cured the Material Breach by the date of the Material Breach Penalty Letter; or (c) whether the alleged material breach could not be cured within the thirty-five (35) day period, but that (i) Walgreens began to take action to cure the material breach; (ii) Walgreens pursued such action with due diligence; and (iii) Walgreens provided to the OIG a reasonable timetable for curing the material breach.

If Walgreens invokes the Dispute Resolution Procedures in this section, the Material Breach Penalty shall be imposed only after an ALJ decision which is favorable to the OIG. The applicable Material Breach Penalty will be based on the number of days between the date of the Material Breach Penalty Letter and the date of the ALB decision favorable to the OIG. Walgreens' election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to impose the Material Breach Penalty upon Walgreens upon the issuance of the ALJ's decision. If the ALJ sustains the OIG's decision and determines that

the imposition of such penalty is authorized, payment of the Material Breach Penalty will be required twenty (20) days after the ALJ issues such a decision notwithstanding that Walgreens may request review of the ALJ decision by the DAB.

#### IX. EFFECTIVE AND BINDING AGREEMENT

Consistent with the provisions in the settlement agreement pursuant to which this CIA is entered, and into which this CIA is incorporated, Walgreens and the OIG agree as follows:

- this CIA shall be binding on the successors, assigns and transferees of Walgreens;
- 2. this CIA shall become final and binding on the date the final signature is obtained on the CIA;
- 3. any material modifications to this CIA shall be made with the prior written consent of the parties to this CIA; and
- 4. the undersigned Walgreens signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA.

# ON BEHALF OF WALGREENS

Sela nen 9/14/99

DIV. Vice PRES.

Title

# ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

LEWIS MORRIS

Assistant Inspector General for Legal Affairs

Office of Inspector General

U.S. Department of Health and Human Services

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